

April 19, 2000

MEMORANDUM

SUBJECT: Response to Public Comments on the Preliminary Risk Assessment for the Organophosphate trichlorfon

FROM: Kylie Rothwell, Chemical Review Manager
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Office of Pesticide Programs

TO: OPP Public Docket for Trichloron
Docket # 34207

Introduction

This document addresses the public comments that were received in response to EPA's Notice of Availability (64 FR 217, November 10, 1999) of the preliminary risk assessment for trichlorfon.

Chemical Specific Comments

Comment: A letter from David Bishop, Golf Course Superintendents Association of America (GCSAA) Director, commented that trichlorfon is useful for controlling pests on golf courses. The GCSAA is surveying nearly 7,500 golf course superintendents to gather data on how trichlorfon is used on golf courses, and intend to compile results by the end of March 2000. GCSAA has volunteered to submit the results of the survey to EPA.

Response: EPA welcomes the efforts of the GCSAA to gather new use practice information for trichlorfon. Such material involvement of a key stakeholder adds greater credibility to the public process.

General Comments Concerning Several OPs and Responses

Comments were received from the Natural Resources Defense Council (NRDC) and they

submitted similar comments regarding other OPs. Their comments are summarized below, followed by our response.

1. Comment Related to Use of FQPA 10X Safety Factor

Comment: The NRDC contends EPA failed to demonstrate that there are sufficient data to justify dropping the use of the 10X safety factor in performing risk assessments for some OPs such as ethyl parathion, methidathion, phosmet, propetamphos, and tetrachlorvinphos. The databases for these chemicals does not contain a developmental neurotoxicity study.

Response: In the case of trichlorfon, the 10X FQPA safety factor was retained because of the occurrence of neuropathology, as well as several data gaps. Neuropathology effects include the presence of organophosphate induced delayed neurotoxicity (OPIDN) and slight axonal degeneration in hens. Data gaps include a prenatal developmental toxicity study and a developmental neurotoxicity study in rats. The Agency determined that the FQPA safety factor should be applied for all non-occupational exposure scenarios and all population subgroups.

OPP has developed criteria for retaining, reducing, and removing the ten-fold safety factor provided for in the FQPA to account for special susceptibility of infants and children to the effects of pesticide exposures. These criteria involve a weight-of-evidence consideration of both the nature and severity of effects observed in young animals, as well as the adequacy of the data base for the chemical. OPP's rationale for these criteria has been reviewed at various stages of development by the SAP. OPP has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor.

In addition, an Intra-Agency workgroup is looking at general considerations regarding the FQPA safety factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor.

Both the SOP and the Intra-Agency workgroup draft guidance document were discussed at the May, 1999 SAP meeting and are available for viewing on the OPP SAP web page: <http://www.epa.gov/scipoly/pesticides/sap>. An FR Notice announcing the availability of these documents for public comment was published in July 1999. Revisions are expected in April 2000. For more information regarding the FQPA safety factor and other science policy issues also see www.epa.gov/pesticides/.

In an FR notice published on August 18, 1999 (Volume 64, Number 151, Page 42945-42947) the Agency announced it is requiring registrants of neurotoxic pesticides to conduct acute, subchronic, and developmental neurotoxicity studies and submit the results to EPA. EPA issued Data Call-In notices to registrants of all neurotoxic pesticides in phases over time, beginning with the cholinesterase-inhibiting organophosphates because of their known neurotoxicity concerns. EPA expects to receive the first studies within 2 years. This Data Call-In program was developed with the advice of the Children's Health Advisory Committee and the

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel.

The question of what constitutes a reliable data base for making decisions related to the FQPA safety factor is being thoroughly reviewed. Once that review process is completed, EPA may need to revisit its assessments and decide how best to incorporate the revised procedures into its ongoing decision making process.

2. Comment Related to Safety Finding

Comment: The NRDC contends that the OP preliminary risk assessments inadequately characterized risks, making it difficult for the Agency to make the “reasonable certainty of no harm” finding, as required by FQPA. According to NRDC, inadequacies in the risk assessments included less protective default assumptions used in exposure assessment models, and failure of EPA to include risk estimates for sentinel populations, such as bystanders and farm worker children. They further stated that since EPA’s preliminary worker risk estimates for some OPs such as phosmet and ethyl parathion indicate risk is presently excessive and cannot be mitigated, these OPs impose unreasonable adverse effects on the environment under FIFRA and the Agency should issue and NOIC and revoke their tolerances.

Response: The preliminary risk assessments represent the best attempt of the Agency to identify and estimate potential risks. A primary goal of the transparency process as initiated by the Tolerance Reassessment Advisory Committee (TRAC) is to solicit comments from knowledgeable and interested parties about our processes and procedures to improve, correct and refine the assessments. EPA intends to complete the risk assessments for the individual OPs, taking into account all comments and new information received in making conclusions and taking regulatory actions. The Agency will soon issue for public comment a draft of its interim early assessment policy for organophosphate pesticides. Updates regarding the status of this and other policy issues can be found on the OPP web site.

It should be noted that the NRDC has previously petitioned the Agency to designate farm children as a major identifiable subgroup under the FQPA. The Agency is currently evaluating the scientific and legal issues raised in that petition. EPA acknowledges that exposures to farm worker children were not evaluated separately, i.e., as a distinct population sub-group. However, based on the limited data currently available to characterize actual pesticide exposure to children of agricultural workers, such as a 1997 biomonitoring study by Loewenherz, Fenske and others (Environ. Health Perspect. 105:1344-1353), we believe that the exposure estimates developed by EPA using the Agency’s Residential Exposure SOPs and other available information are reasonably inclusive of the exposures likely to be experienced by this sub-group.

EPA is concerned about the disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below.

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding

exposure of children to pesticides. The studies are looking at major types of exposure (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing, on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Finally, based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children as agricultural workers.

3. Comment Related to Aggregate Exposure

Comment: The NRDC contends that many of the OP preliminary risk assessments failed to assess aggregate dietary and non-dietary exposures as required by FQPA. In some cases (ethyl parathion and phosmet) the drinking water risk contribution was not estimated since the preliminary risk contribution from food indicated potentially excessive risk. In cases where residential exposure/risk was estimated, some of the assumptions used in estimating residential exposure were again questioned. The NRDC objected to the EPA practice of not including a residential exposure/risk component for those OP with no registered residential uses. They rationalized that residential exposure is possible for the OPs as a result of drift, contaminated air, and other inadvertent routes of exposure.

Response: The issues raised here regarding our approach to aggregate and residential risk assessment are among those scientific issues previously identified by the Agency as needing further delineation. The Agency has not yet finalized its methodologies, and so the preliminary risk assessments addressed these areas for some of the OPs to the extent possible using interim guidance. The Agency has continued with the development of additional guidance on its approach to assessing aggregate risk, and draft policy documents were issued for public comment in January 1999, with additional policy documents concerning the Agency's approach to drinking water assessment expected early in 2000. Revised policy and guidance which considers the public comments received will follow. The approach to residential exposure and risk assessment was discussed at the SAP in September 1999. See also the Federal Register Notice of October 29, 1998 regarding the science policy papers, and the OPP web site at www.epa.gov/pesticides.

4. Comment Related to Cumulative Risk

Comment: The NRDC contends that EPA has not met its public health responsibility nor the FQPA mandate by not including cumulative risk estimates for the OPs. The OPs are known to demonstrate a common mechanism of human neurotoxicity through inhibition of the enzyme cholinesterase.

Response: EPA agrees that based on current scientific information organophosphate pesticides should be considered to operate via a common mechanism of toxicity—cholinesterase inhibition. In the Federal Register of August 6, 1998 (63 FR 42031 (FRL-5797-9)), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides." In developing this document, the Agency solicited advice from the FIFRA Scientific Advisory Panel (SAP) in February 1997; a year later (March 1998), OPP reported its progress to the SAP. The guidance document describes the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. The 60-day comment period ended October 8, 1998. Revised guidance was issued in February, 1999 and was the one of the subjects of discussion at the SAP held in September 1999.

With respect to the comments that EPA has not considered common mechanism in these early assessments, the Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed. Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, the International Life Sciences Institute (ILSI) is independently exploring appropriate methods and developing a framework for performing a cumulative risk assessment. ILSI held a workshop on this subject in September 1998, and the results of this work has been considered by the Agency (see "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides."). The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document. Cumulative risk assessment methodology issues of pesticides that have a common mechanism of toxicity will again be a topic at the December 8, 1999 SAP meeting.

Until methodology is finalized, EPA intends to complete risk assessments for individual OPs and proceed with the public process for development of risk mitigation strategies. The Agency will soon issue for public comment a draft of its interim early assessment policy for organophosphate pesticides. Updates regarding the status of this and other policy issues can be found on the OPP web site.